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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/616,276	07/09/2003	Torsten Hoffmann	20693 US2	9901

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HOFFMANN-LA ROCHE INC.
PATENT LAW DEPARTMENT
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EXAMINER	
ROBINSON, BINTA M	

ART UNIT	PAPER NUMBER
1625	

DATE MAILED: 05/18/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/616,276	HOFFMANN ET AL.	
	Examiner	Art Unit	
	Binta M. Robinson	1625	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-15* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *13* is/are allowed.

6)☒ Claim(s) *1-12,14 and 15* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☒ Certified copies of the priority documents have been received in Application No. 0904059.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *10/6/03*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Detailed Action

Claims 4 and 8 are objected to because of the following informalities: the term "rig" is a misspelling of the term "ring". Appropriate correction is required.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 14 and 15 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. A method of inhibiting a NK-1 receptor in an individual comprising administering to the individual a compound of claim 1 is not a treatment of a disease. Regarding a method of inhibiting NK-1 receptors in an individual or treating a disease responsive to antagonist modulation of the NK-1 receptor in a patient, the applicant is claiming future developments that are not yet known at the time of invention. The specific diseases being treated by this inhibition or modulation of the NK-1 receptor is not being stated. There is no reasonable assurance that these compounds will have all of the alleged properties or have the applicants supplied the supporting data. The inhibition or modulation of an enzyme must be related to a disease that needs to be improved and this specific disease needs to be recited.

There are many factors to be considered when determining whether there is sufficient evidence to support a determination that a disclosure does not satisfy

the enablement requirement and whether any necessary experimentation is "undue". These factors include 1)the breadth of the claims, 2) the nature of the invention, 3) the state of the prior art, 4) the level of one of ordinary skill, 5) the level of predictability in the art 6) the amount of direction provided by the inventor 7) the existence of working examples, and 8) the quantity of experimentation needed to make or use the invention based on the content of the disclosure. In re Wands, 858 F. 2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988).

The Nature of the Invention

The invention relates to amine oxide compounds that are inhibitors of the NK1 receptor.

The State of the Prior Art.

The state of the prior art is that the central and peripheral actions of the mammalian tachykinin substance P have been associated with numerous inflammatory conditions including migraine, rheumatoid arthritis, asthma, and inflammatory bowel disease as well as mediation of the emetic reflex and the modulation of central nervous system (CNS) disorders such as Parkinson's disease (Nerosci. Res., 1996, 7, 187-214) (See Reference U), anxiety (Can. J. Phys. 1997, 75, 612-621) (See Reference V) and depression (Science, 1998, 281, 1640-1645) (See Reference W). Neurokin 1 receptor antagonists are being developed for the treatment of a number of physiological disorders, such as certain forms of urinary incontinence as described in Eur. J. Pharmacol., 383 (3), 297-303, (1999) (See Reference X) and for treating a

psychoimmunologic or a psychosomatic disorder. (See US 5972938) (See Reference A).

The predictability or lack thereof in the art

It is noted that the pharmaceutical art is unpredictable as discussed below, requiring each embodiment to be individually assessed for physiological activity. In re Fisher, 427 F. 2d 833, 166 USPQ 18 (CCPA 1970) indicates that the more unpredictable an area is, the more specific enablement is necessary in order to satisfy the statute. In the instant case, the claimed invention is highly unpredictable since one skilled in the art would recognize that in regards to therapeutic effects of NK-1 antagonists, whether or not the NK-1 was inhibited would affect the possible treatment of any disease.

Hence, in the absence of a showing of correlation between specific diseases related to the inhibition of NK-1, one of skill in the art is unable to fully predict possible results from the administration of the compound of claim 1 due to the unpredictability of the role of NK-1, i. e. whether or not inhibition would be beneficial for the treatment of actual diseases. The applicant does not provide experimental data of NK-1 inhibition assays or results relating NK-1 inhibition to the treatment of specific diseases, but only provides NK-1 binding assays. The prior art notes that tachykin receptor antagonists may have usefulness in the treatment of specific diseases, such as pain, headache, Alzheimer's disease, multiple sclerosis, (See J. Auton. Pharmacol. 13, 23-93, 1993) but not all future diseases that are not currently known.

The nature of the pharmaceutical arts is that it involves screening in vitro and in vivo to determine which compounds exhibit the desired pharmacological activities. There is no absolute predictability even in view of the seemingly high level of skill in the art. The existence of these obstacles establishes that the contemporary knowledge in the art would prevent one of ordinary skill in the art from accepting any therapeutic regimen on its face.

The amount of direction or guidance present

The direction present in the instant specification is that the compounds of claim 1 can inhibit NK-1 which helps in the treatment for various diseases, such as central nervous system disorders. However, the specification does not provide experimental data and results of NK-1 inhibition assays in relation to the treatment and prevention of specific diseases. The applicant only provides binding assays regarding NK-1.

The presence or absence of working examples

There are no specific working examples of any diseases listed in the specification as being connected to the modulation of NK-1 being treated by the claimed compounds. The compounds which are disclosed in the specification have no pharmacological data regarding the treatment of any disease in terms of the possible treatment of NK-1 mediated diseases that would require NK-1 inhibition. The specification fails to provide working examples of how the diseases listed in the specification can be treated by the inhibition of NK-1, and again, there is no correlation between the diseases listed and the inhibition of NK-1.

The breadth of the claims

The breadth of the claims is that the compound of claim 1 can treat any NK-1 mediated disease.

The quantity of experimentation needed

The quantity of experimentation needed is undue experimentation. One of skill in the art would need to determine what diseases would be benefited by the inhibition of NK-1 and would furthermore then have to determine whether the claimed compounds would provide treatment of the disease by the inhibition of NK-1.

The level of skill in the art

The level of skill in the art is high. However, due to the unpredictability in the pharmaceutical art, it is noted that each embodiment of the invention is required to be individually assessed for physiological activity by in vitro and in vivo screening to determine which compounds exhibit the desired pharmacological activity and which diseases would benefit from this activity.

Thus, the specification fails to provide sufficient support for the broad use of the compound of the claim 1 for the treatment of NK-1 mediated diseases. As a result, one of skill in the art would be necessitated to perform an exhaustive search for NK-1 mediated diseases which can be treated by the compound of claim 1 in order to practice the claimed invention.

Genentech Inc. v. Novo Nordisk A/S (CA FC) 42 USPQ2d 1001 , states that " a patent is not a hunting license. It is not a reward for search , but compensation for its successful conclusion" and "[p]atent protection is granted in return for an enabling

disclosure of an invention, not for vague intimations of general ideas that may or may not be workable".

Therefore, in view of the Wands factors and In re Fisher (CCPA 1970) discussed above, to practice the claimed invention herein, a person of skill in the art would have to engage in undue experimentation to test which NK-1-mediated diseases can be treated by the compound encompassed in the instant claims, with no assurance of success.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 5, 9, and 14 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A. Claim 5 recites the limitation "Ie" in line 3, page 49, of the claims filed 7/9/03. There is insufficient antecedent basis for this limitation in the claim.

B. Claim 9 recites the limitation "Id" in line 3, page 50, of the claims filed 7/9/03. There is insufficient antecedent basis for this limitation in the claim.

C. In claim 14, line 2, page 50 of the claims filed 7/29/03, the phrase "individual compound" is indefinite. It is not clear if the applicant is claiming an "individual compound" or that this compound is being administered to an individual host? The applicant needs to claim administration of the compound of claim 1 to a host, via administration of an effective amount of the compound of claim 1.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent

and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claim 1 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1 of U.S. Patent No. 6297375 in further view of Patterson (Ca 122:281401). Although the conflicting claims are not identical, they are not patentably distinct from each other because 6297375 teaches the free amine drugs of the instant prodrug N-oxide compounds that are claimed.

US Patent 6297375 claimed the drug of the instant claims. See claim 1, where R4 is –N(R5), or R4 forms a N containing ring optionally substituted by R6, R5 is hydrogen, or lower alkyl, X is –N(R5)C(O)-, R is lower alkyl, lower alkoxy, halogen or trifluoromethyl, R1 is halogen or hydrogen, and when p is 1, R1 may be taken together with R to form –CH=CH-CH=CH-, R2 and R2' are independently hydrogen, halogen, trifluoromethyl, lower alkoxy, or cyano, when n is 1, R2 and R2' may in addition to the above substituents form –CH=CH-CH=CH-, unsubstituted or substituted by one or two substituents selected from lower alkyl or lower alkoxy, R3 and R3' are hydrogen, hydrogen, n, p and q are 1 to 4, m is 1 or 2, R6 is hydrogen, lower alkyl, hydroxy.

The N-oxide compound of the 6297375 free amino drug is the prodrug form of such drug. See page 2 of the specification as well as Patterson (Ca 122:281401). The

difference between the Bos ('375) drug and the instantly claimed prodrug is that instead of an oxygen being bound to the amino substituent on the pyridyl ring of the compound, the instant claim is drawn to a free amino functional group substituent on the pyridyl ring of the compound. N-Oxides being prodrugs over the free amine drug compounds is prima facie obvious. One having ordinary skill in the art is deemed to be aware of all the prodrug forms conventional to the art.

Since a prodrug is a pharmaceutical formulation for delivery of a drug and dependent on the drug for utility, prodrugs are prima facie obvious over the conventional drug.

Claims 1-2 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-4 of U.S. Patent No. 6479483 in further view of Patterson (Ca 122:281401). Although the conflicting claims are not identical, they are not patentably distinct from each other because 6479483 teaches the free amine drugs of the instant prodrug N-oxide compounds that are claimed.

US Patent 6479483 claimed the drug of the instant claims. See claim 1, where R4 is –N(R5), or R4 forms a N containing ring optionally substituted by R6, R5 is hydrogen, or lower alkyl, X is –N(R5)C(O)-, R is lower alkyl, R1 is halogen or hydrogen, and when p is 1, R1 may be taken together with R to form –CH=CH-CH=CH-, R2 and R2' are independently hydrogen, halogen, trifluoromethyl, lower alkoxy, or cyano, when n is 1, R2 and R2' may in addition to the above substituents form –CH=CH-CH=Ch-, unsubstituted or substituted by one or two substituents selected from lower alkyl or

lower alkoxy, R3 and R3' are hydrogen, hydrogen, n, p and q are 1 to 4, m is 1 or 2, R6 is hydrogen, lower alkyl, hydroxy.

The N-oxide compound of the 6479483 free amino drug is the prodrug form of such drug. See page 2 of the specification as well as Patterson (Ca 122:281401). The difference between the ('483) drug and the instantly claimed prodrug is that instead of an oxygen being bound to the amino substituent on the pyridyl ring of the compound, the instant claim is drawn to a free amino functional group substituent on the pyridyl ring of the compound. N-Oxides being prodrugs over the free amine drug compounds is prima facie obvious. One having ordinary skill in the art is deemed to be aware of all the prodrug forms conventional to the art.

Since a prodrug is a pharmaceutical formulation for delivery of a drug and dependent on the drug for utility, prodrugs are prima facie obvious over the conventional drug.

Claim 29 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 2, 4, 15, 16, 19 of U.S. Patent No. 2003/0083345 application in further view of Patterson (Ca 122:281401) and claims 1-28 are rejected over claim 19 of U. S. Patent application 2003/0083345 in further view of Patterson. Although the conflicting claims are not identical, they are not patentably distinct from each other because 2003/0083345 teaches a method of treating or preventing brain, spinal or nerve injury, which are diseases that are responsive to antagonist modulation of the NK-1 receptor, with the free amine drugs of the instant prodrug N-oxide compounds that are claimed as well as with the prodrug N-oxide

compounds of the instant claims, as well as a pharmaceutical composition containing said drug or prodrug.

US Patent application 2003/0083345 claimed a method of treating or preventing brain, spinal or nerve injury, with the drug of the instant claims as well as a subgenus of the instant N-oxide prodrugs as well as a pharmaceutical composition containing the said drug or N-oxide prodrugs. See claim 1, where R is selected from the group consisting of hydrogen, lower alkyl, lower alkoxy, halogen and trifluoromethyl, R1 is hydrogen or halogen, or R and R1 may be together –CH=CH-CH=CH-, R2 andR2' are independently from each other hydrogen, halogen, trifluoromethyl, lower alkyl, lower alkoxy or cyano; or R2 and R2' may be together –CH=CH-CH=CH-, optionally substituted by one or two substituents selected from lower alkyl, halogen or lower alkoxy; R3 is independently from each other if occurring twice, hydrogen, lower alkyl or may, R4 is selected from the group consisting of hydrogen, -N(R5), or an nitrogen containing ring substituted by R6, and R6 is hydrogen, hydroxy, lower alkyl, R4 can be N+OR11R12 R11', and R11' is –(CH2)pOR12 or lower alkyl, or wherein R12 is lower alkyl, or R11 and R11' form together with the N-atom to which they are attached a cyclic tertiary amine optionally substituted with R13, wherein R13 is hydrogen, hydroxy, lower alkyl, lower alkoxy, -(CH2)pOH, -COOR3, -CON(R3)2, -N(R3)CO-lower alkyl or –C(O)R3, R5 is lower alkyl, and R4 is –N(R5), or R4 forms a N containing ring optionally substituted by R6, R5 is hydrogen, or lower alkyl, X is –N(R5)C(O)-, R is lower alkyl, R1 is halogen or hydrogen, and when p is 1, R1 may be taken together with R to form –CH=CH-CH=CH-, R2 and R2' are independently hydrogen, halogen, trifluoromethyl,

lower alkoxy, or cyano, when n is 1, R6 is hydrogen, hydroxy, lower alkyl, n, p and q are 1 to 4, m is 1 or 2, R6 is hydrogen, lower alkyl, hydroxy.

The N-oxide compound of the '345 free amino drug is the prodrug form of such drug. See page 2 of the specification as well as Patterson (Ca 122:281401). The difference between the ('345) method of treating specific diseases that are responsive to antagonist modulation of the NK-1 receptor with the drug and pharmaceutical composition containing said drug and the instantly claimed method of treating diseases that are responsive to antagonist modulation of the NK-1 receptor with the prodrug and the pharmaceutical composition containing said prodrug is that instead of an oxygen being bound to the amino substituent on the pyridyl ring of the compound, the instant claim is drawn to a free amino functional group substituent on the pyridyl ring of the compound. N-Oxides being prodrugs over the free amine drug compounds is prima facie obvious. One having ordinary skill in the art is deemed to be aware of all the prodrug forms conventional to the art.

Since a prodrug is a pharmaceutical formulation for delivery of a drug and dependent on the drug for utility, a method of treating with prodrugs and pharmaceutical compositions containing said prodrugs are prima facie obvious over the method of treating with the conventional drug and the pharmaceutical compositions containing the conventional drug.

The difference between the '345 method of treating with the prodrug and pharmaceutical composition containing said prodrug and the instantly claimed method of treating with the instant prodrug and the pharmaceutical composition containing said

prodrug is that the '345 method of treating specific diseases of preventing brain, spinal or nerve injury is with a subclass of the genus prodrugs of the instant claims and the pharmaceutical composition contains a subclass of the genus of instant prodrugs.

It would have been obvious to one of ordinary skill in the art to select various known radicals within a genus to prepare structurally similar compounds with which to treat diseases responsive to antagonist modulation of the NK-1 receptor and to prepare pharmaceutical compositions containing the said prodrugs. Accordingly, the method of treating and pharmaceutical composition are deemed unpatentable therefrom in the absence of a showing of unexpected results for the claimed method of treating and pharmaceutical composition over those of the generic '345 method of treating and pharmaceutical composition.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims, 1, 3, 2, 5, 6, 7, respectively are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 4, 3, 1, 3, 4 respectively of U.S. Patent No. 6593472. Although the conflicting claims are not identical, they are not patentably distinct from each other because the '472 patent is claiming a subgenus of the instant genus of N-oxide prodrugs as well as a subgenus of species of the instant N-oxide prodrugs.

'472 claimed a subgenus of the instant N-oxide prodrugs. See the compound of formula I at column 33 where the radicals are defined.

The difference between the '472 claims and the instant claims is that '472 is claiming a subgenus of the instant prodrugs.

It would have been obvious to one of ordinary skill in the art to select various known radicals within a genus to prepare structurally similar compounds. For example, see the compound of claim 5, at column 33. Accordingly, the instant compounds are deemed unpatentable therefrom in the absence of a showing of unexpected results for the claimed compounds over those of the generic '472 compounds.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-7, 9, 10-11 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 5-17 of U.S. Patent No. 6593472. Although the conflicting claims are not identical, they are not patentably distinct from each other because the compound species in claims 5-17 anticipate the genus in instant claims.

Claim 13 is allowable.

The IDS 10/26/03 has been considered. The references that have been crossed out will not be considered until provided to the examiner.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Binta M. Robinson whose telephone number is (703) 306-5437. The examiner can normally be reached on M-F (9:30-6:00).

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Mr. Joseph McKane, can be reached at (703) 308-4537.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone numbers are (703) 308-1235 and (703) 308-0196.

A facsimile center has been established. The hours of operation are Monday through Friday, 8:45AM to 4:45PM. The telecopier numbers for accessing the facsimile machine are (703) 308-4242, (703) 305-3592, and (703) 305-3014.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Binta M. Robinson whose telephone number is 1(571)272-0692. The examiner can normally be reached on M-F (9:30-6:00).

Binta Robinson

May 17, 2004

JOHANN RICHTER
SUPERVISORY PATENT EXAMINER
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